

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	C.A. No. 21-1015 (GBW)
v.)	
)	DEMAND FOR JURY TRIAL
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
<hr/>		
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR
PARTIAL SUMMARY JUDGMENT NO. 3 REGARDING
ITS BREACH OF CONTRACT CLAIM

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Dated: December 11, 2023

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I. INTRODUCTION

The Court should grant summary judgment in favor of plaintiff Nippon Shinyaku Co., Ltd. (“NS”) regarding its breach of contract claim (D.I. 86, Claim I) and award NS \$ [REDACTED] in damages because the Federal Circuit has already held, as a matter of law, that defendant Sarepta Therapeutics, Inc. (“Sarepta”) breached the relevant contract between the parties—the Mutual Confidentiality Agreement (“MCA”)—by filing *inter partes* review petitions in contravention of the MCA’s forum selection clause. No factual disputes remain on this claim.

II. NATURE AND STAGE OF THE PROCEEDINGS

NS initiated this action on July 13, 2021 asserting claims for, *inter alia*, patent infringement and breach of contract. On that same day, NS filed a motion for preliminary injunction to enjoin Sarepta’s improper filing of IPR petitions. D.I. 4. After this Court denied the motion for preliminary injunction, NS appealed. D.I. 55. The Federal Circuit reversed and remanded with instructions that this Court enter the preliminary injunction. *See* D.I. 92-1 at 16.

III. CONCISE STATEMENT OF FACTS

NS incorporates by reference its concise statement of facts filed herewith.

IV. SUMMARY OF THE ARGUMENT

The Court should grant summary judgment in favor of NS regarding its breach of contract claim because:

a. The Federal Circuit has held as a matter of law that Sarepta breached the MCA’s forum selection clause by filing IPR Petitions regarding the NS Patents at the PTAB in contravention thereof, and this ruling is law of the case.

b. Even if it is not deemed law of the case, the Federal Circuit’s holding was correct as a matter of law.

c. There is no dispute regarding damages given that [REDACTED]

V. ARGUMENT

A. The Federal Circuit’s Holding Of Breach Is Law of the Case.

“Under the law of the case doctrine, a panel decision on a preliminary injunction motion constitutes binding precedent . . . when the record before the panel was ‘sufficiently developed and the facts necessary to shape the proper legal matrix we[re] sufficiently clear.’” *Comcast of Me./N.H., Inc. v. Mills*, 988 F.3d 607, 612 (1st Cir. 2021) (citation omitted). Against this backdrop numerous courts have determined that appellate court rulings on legal issues underlying a preliminary injunction are subject to the law of the case doctrine. *See, e.g., Ass’n of N.J. Rifle & Pistol Clubs Inc. v. Att’y Gen. N.J.*, 974 F.3d 237, 246 (3d Cir. 2020), *rev’d on other grounds by* 142 S. Ct. 2894 (2022) (holding where appellate panel reaches “ultimate merits of the dispute” on preliminary injunction appeal holding on merits constitutes law of case); *Fish v. Schwab*, 957 F.3d 1105, 1141 (10th Cir. 2020) (holding it makes “eminent sense” to apply law of case doctrine where preliminary injunction appellate court ruling was a “definitive, fully considered legal decision based on a fully developed factual record”). Indeed, absent “extraordinary circumstances” not present here—*i.e.*, “(1) there has been an intervening change in the law; (2) new evidence has become available; or (3) reconsideration is necessary to prevent clear error or a manifest injustice”—the law of the case doctrine governs preliminary injunction legal issues. *See Ass’n of N.J. Rifle & Pistol Clubs*, 974 F.3d at 246.

Here, all the elements for application of the law of the case doctrine are satisfied. The Federal Circuit had a fully developed record from which to decide the legal question of contract interpretation presented by NS’s breach of contract claim—namely, whether Section 10 of the MCA mandates that any Potential Actions arising under U.S. law relating to patent invalidity to be brought in the District of Delaware during the relevant time period. The Federal Circuit

undertook this examination and legal analysis based on a record which has not changed throughout this litigation and unequivocally held as a matter of law that “the plain language of the forum selection clause in Section 10 of the MCA” was dispositive of the issue of breach and “resolve[d] the dispute.” Fed. Cir. Op. (D.I. 92-1) at 9. Specifically, after reciting the language of Section 10 of the MCA—which the Federal Circuit noted “states clearly” “all Potential Actions arising under U.S. law relating to patent infringement or invalidity” must be filed in the U.S.D.C. for the District of Delaware—the Federal Circuit held “[t]he MCA’s forum selection clause is . . . unambiguous.” *Id.* at 9-10. Accordingly, the Federal Circuit held Sarepta’s filing of IPR Petitions “contravened the plain language of the forum selection clause in Section 10 of the MCA” and found as a “matter of law” that “Section 10 of the MCA preclude[d] the filing of IPR petitions.” *Id.* at 10, 14.

The Federal Circuit’s legal ruling is thus law of the case. And, there is no reason for this Court to revisit the Federal Circuit’s holding now as doing so would eviscerate the policy underlying the law of the case doctrine that “courts [should] refrain from re-deciding issues that were resolved earlier in the litigation.” *Pub. Interest Research Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 116 (3d Cir. 1997).

B. No Extraordinary Circumstances Exist Here to Depart From Application of the Law of the Case Doctrine.

Disregarding the current law of the case (the Federal Circuit’s determination that Sarepta breached the MCA’s forum selection clause) would be inappropriate where, as here, none of the requisite “extraordinary circumstances” for doing so are present.

First, the record is devoid of evidence this Court’s prior holding was “clearly erroneous” or would work a “manifest injustice.” Instead, at most, Sarepta will merely recycle arguments regarding legal interpretation of the MCA that they raised (or could have raised) the first time around. This is insufficient to justify the extraordinary remedy of disregarding the law of the case.

See DeJesus v. Knight Indus. & Assocs., Inc., No. 10-07434, 2016 WL 1555793, at *7 (E.D. Pa. Apr. 18, 2016) (“That Plaintiffs disagree with the decision does not render it ‘clearly erroneous’ or subject them to a manifest injustice.”) (citation omitted); *Smith Int’l, Inc. v. Hughes Tool Co.*, 759 F.2d 1572, 1578-79 (Fed. Cir. 1985) (affirming application of law of case doctrine and declining to consider evidence and arguments that could have originally been presented).

Second, there is no new evidence adduced in discovery in this action which impacts the Federal Circuit’s prior legal determination—a determination that begins and ends with the plain language of the MCA itself. *See* D.I. 92-1 at 9 (“plain language of the forum selection clause in Section 10 of the MCA resolves the dispute”) *id.* at 10 (making finding based on “[p]lain language of Section 10” of the MCA); *id.* at 11 (“We conclude as *a matter of law* that the forum selection clause in Section 10 of the MCA precludes the filing of IPR petitions during the two-year period following the expiration of the Covenant Term on June 21, 2021.”) (emphasis added).

Third, there is no new supervening law that has been announced which alters the Federal Circuit’s prior legal holding. The Federal Circuit relied on well-established bedrock Delaware contract law that has not changed. *See* D.I. 92-1 at 9 (reciting relevant law).

C. Law of Case Doctrine Aside, the Court Should Find as a Matter of Law that Sarepta Breached the MCA.

Even if the Court declines to apply the law of the case doctrine, the Court should hold as a matter of law that Sarepta breached the MCA. Each element for a breach of contract claim—“(1) the existence of a contract; (2) the breach of an obligation imposed by the contract; and (3) resulting damage to the plaintiff”—is satisfied. *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 394 (D. Del. 2019).

First, it is undisputed that the MCA is a valid and enforceable contract between NS and Sarepta. NS’s Statement of Facts (“SOF”), ¶ 2.

Second, Sarepta has breached the forum selection clause of Section 10 of the MCA by filing its IPR Petitions at the PTAB. Here, the MCA’s forum selection clause is clear and unambiguous. *See* SOF ¶¶ 5, 7. An objective, reasonable third party would understand that Section 10 of the MCA prohibits the parties from filing *any* Potential Actions arising under U.S. law relating to patent invalidity anywhere outside of this District. SOF ¶ 6. By filing patent invalidity challenges to the NS Patents before the PTAB instead of this Court, Sarepta breached the MCA. The plain meaning of the MCA does not support any other interpretation. *See* SOF ¶¶ 5, 6.

As Sarepta acknowledges, the IPR Petitions “challeng[e] the patentability of certain NS Patents.” Sarepta Opp’n to Mot for P.I. (D.I. 18) at 7. The IPR Petitions thus indisputably qualify as patent disputes between NS and Sarepta. The IPR Petitions were filed with an administrative agency—the PTAB.⁴ *See, e.g., United States v. Arthrex, Inc.*, 594 U.S. ___, 141 S. Ct. 1970 (2021). And the IPR Petitions are in connection with the Parties’ development and commercialization of therapies for [DMD] because they challenge the validity of the NS Patents, which relate to DMD therapies. The IPR Petitions thus fall squarely within the definition of “all Potential Actions.” Nothing in the remainder of the forum selection clause narrows or limits its scope.

The language in the forum selection clause stating that “neither Party will contest personal jurisdiction or venue **in the District of Delaware** and that neither Party will seek to transfer the Potential Actions on the ground of *forum non conveniens*,” (MCA, § 10), also does not narrow its scope. On its face, the sentence merely concerns actions filed “in the District of Delaware”—it says nothing about actions filed outside the District of Delaware, either in other district courts or

⁴ They were also filed after the Effective Date of June 1, 2020.

before administrative agencies. Indeed, the Federal Circuit has found the presence of such language specific to district court litigations in forum selection clauses does not preclude the extension of a forum selection clause to PTAB proceedings. *See Dodocase VR, Inc. v. MerchSource, LLC*, 767 F. App'x 930, 932 (Fed. Cir. 2019) (affirming district court's holding that plaintiff "was likely to succeed on the merits of its claim that [defendant] violated the forum selection clause of the MLA by filing the PTAB petitions" despite forum selection clause referring to district court subject matter and personal jurisdiction).

Third, as described below, there is no dispute that NS has suffered damages as a result of Sarepta's breach. *Cf.* SOF ¶ 12.

D. The Amount of Damages Arising from Sarepta's Breach Is Undisputed.

The final element of a breach of contract claim is damages resulting from the breach. Here, this element (and the amount thereof) is undisputed for purposes of the instant motion as noted above. It is undisputed that NS incurred attorneys' fees in connection with its breach of contract claim in this action and in connection with defending against Sarepta's IPR Petitions filed in contravention of the MCA's forum selection clause. *See* SOF ¶ 12. Although the parties' experts initially disputed the amount of fees attributable to the breach of contract claim, for purposes of the instant motion, [REDACTED]. SOF ¶¶ 13, 14. Accordingly, there is no dispute amongst the parties regarding the amount of damages NS is due if the Court determines—as it should—that Sarepta breached the MCA.

VI. CONCLUSION

For the foregoing reasons, the Court should grant partial summary judgment in favor of NS regarding its breach of contract claim and award NS \$ [REDACTED] in damages for this claim.

Dated: December 11, 2023

Respectfully submitted,

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